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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,887	07/17/2003	Ulrich Posanski	4-20017E	7665
1095	7590	09/11/2007		
NOVARTIS CORPORATE INTELLECTUAL PROPERTY ONE HEALTH PLAZA 104/3 EAST HANOVER, NJ 07936-1080			EXAMINER ROBERTS, LEZAH	
			ART UNIT	PAPER NUMBER
			1614	
			MAIL DATE	DELIVERY MODE
			09/11/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/623,887	<b>Applicant(s)</b> POSANSKI, ULRICH	
	<b>Examiner</b> Lezah W. Roberts	<b>Art Unit</b> 1614	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 June 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 11-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

This Office Action is in response to the Amendment filed June 14, 2007. All previous rejections have been withdrawn unless stated below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. This action is made Non-Final.

### *Claims*

#### **Claim Rejections - 35 USC § 103 – Obviousness (New Rejections)**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1) Claims 11-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cavanak (US 5,639,724) in view of Amselem et al. (US 5,576,016).

Cavanak discloses pharmaceutical compositions comprising cyclosporine as an active ingredient, a fatty acid triglyceride, a glycerol fatty acid partial ester or propylene glycol or sorbitol complete or partial ester, preferably, and a tenside having an HLB of at least 10. Tensides include polyoxyethylene-sorbitan-fatty acid esters. Glycerides include corn oil. The carrier does not require the presence of additional solvents, co-solvents or solubilizers. The carriers also increase bioavailability. The compositions may have a formulation C having a) an active ingredient (about 17%); b) a fatty acid triglyceride (about 33%); c) a glycerol fatty acid partial ester or propylene glycol (about 33%) and e) a tenside (about 17%), (col. 13, lines 46-60, also see Example 6 for percentages). The compositions may be encapsulated in hard or soft gelatin capsules (col. 7, lines 23-33). The reference differs from the instant claims insofar as it discloses cyclosporin as the active agent and not a water insoluble drug excluding cyclosporin.

Amselem et al. disclose compositions as carriers for insoluble drugs such as cyclosporine and etoposide. The drugs' insolubility makes their formulation for delivery difficult. The compositions comprise triglycerides, surfactants such as Tween, and phospholipids as well as other components (col. 4, line 23 to col. 9, line 1). The reference differs from the instant claims insofar as it does not disclose the components in the recited percentages.

It would have been obvious to one of ordinary skill in the art to have incorporated other important water insoluble drugs in place of cyclosporin into the carriers of the primary reference motivated by the desire make delivery of the drugs less difficult and

increase bioavailability of the drugs as disclosed by the primary and secondary references.

2) Claims 11-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Constantinides (WO 93/02665) in view of Gregory et al. (US 5,262,179).

Constantinides discloses micro-emulsions comprising a long chain fatty acid triglyceride including neutral oil, low HLB surfactants including long chain-fatty acid monoglycerides, high HLB surfactants including polyoxyethylene sorbitan and a water soluble drug (pages 4-6). The carrier systems have advantages including, components such as ethanol may be avoided and they increase solubility as well as other advantages (page 2, lines 8-24). The long chain fatty acid triglyceride and low HLB surfactant together comprise 70 to 95% of the compositions in a 4:1 to 2:1 ratio. The high HLB surfactant comprises 7.5 to 15% by weight of the compositions (page 12). Other components may also be incorporated into the compositions. The compositions may be formulated into oral compositions including soft gelatin capsules (page 15, lines 15-22). The reference differs from the instant claims insofar as it does not disclose the drug is water insoluble.

Gregory et al. is used to disclose the difficulty of delivering ibuprofen. Ibuprofen is water insoluble and often causes gastric irritation when administered in solid or suspended form, especially in the doses required to treat rheumatic disease. Solutions of water-soluble ibuprofen salts have an unpleasant burning taste and, for that reason, their use generally has been avoided. Many attempts have been made to improve the

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solubility and taste of ibuprofen especially in its free acid form (col. 1, lines 14-30). The reference differs from the instant claims insofar as it does not disclose the surfactant, co-surfactant and oil carrier of the instant claims.

It would have been obvious to one of ordinary skill in the art to have incorporated water insoluble drugs such as ibuprofen into the carriers of the primary reference motivated by the desire to improve solubility of the ibuprofen as disclosed by the secondary and primary references.

Claims 11-22 are rejected.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lezah Roberts  
Patent Examiner  
Art Unit 1614



Frederick Krass  
Primary Examiner  
Art Unit 1614

